PART 37—SPECIFICATIONS FOR MEDICAL EXAMINATIONS OF UNDERGROUND COAL MINERS

Subpart—Chest Roentgenographic Examinations

Subpart—Autopsies

AUTHORITY: Sec. 203, 83 Stat. 763; 30 U.S.C. 843, unless otherwise noted.

SOURCE: 43 FR 33715, Aug. 1, 1978, unless otherwise noted.

Subpart—Chest Roentgenographic Examinations

§ 37.1 Scope.

The provisions of this subpart set forth the specifications for giving, interpreting, classifying, and submitting chest radiographs required by section 203 of the Act to be given to underground coal miners and new miners.

[77 FR 56725, Sept. 13, 2012]

§ 37.2 Definitions.

Any term defined in the Federal Mine Safety and Health Act of 1977 and not defined below will have the meaning given it in the Act. As used in this subpart:

Act means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801, *et seq.*).

Chest radiograph means a single posteroanterior radiographic projection or radiograph of the chest at full inspiration recorded on either film or digital radiography systems.

Convenient time and place with respect to the conduct of any examination under this subpart means that the examination must be given at a reasonable hour in the locality in which the miner resides or a location that is equally accessible to the miner. For example, examinations at the mine during, immediately preceding, or immediately following work and a ''no appointment'' examination at a medical facility in a community easily accessible to the residences of a majority of the miners working at the mine, will be considered of equivalent convenience for purposes of this paragraph.

Digital radiography systems, as used in this context, include both Digital Radiography (DR) and Computed Radiography (CR).

(1) *Computed radiography (CR)* is the term for digital X-ray image acquisition systems that detect X-ray signals using a cassette-based photostimulable storage phosphor. Subsequently, the

cassette is processed using a stimulating laser beam to convert the latent radiographic image to electronic signals which are then processed and stored so they can be displayed.

(2) *Digital radiography (DR)* is the term used for digital X-ray image acquisition systems in which the X-ray signals received by the image detector are converted nearly instantaneously to electronic signals without movable cassettes.

ILO Classification means the below-referenced classification of radiographs of the pneumoconioses system devised by an international committee of the International Labour Office (ILO), including a complete set of standard film radiographs or digital chest image files available from the ILO or other set of chest image files accepted by NIOSH as equivalent.

MSHA means the Mine Safety and Health Administration, Department of Labor.

Miner means any individual including any coal mine construction worker who is working in or at any underground coal mine, but does not include any surface worker who does not have direct contact with underground coal mining or with coal processing operations.

NIOSH means the National Institute for Occupational Safety and Health (NIOSH), located within the Centers for Disease Control and Prevention (CDC). Within NIOSH, the Division of Respiratory Disease Studies (DRDS), Box 4258, Morgantown, WV 26504, formerly called the Appalachian Laboratory for Occupational Safety and Health, is the organizational unit that has programmatic responsibility for the chest radiographic examination program.

NIOSH representative means employees of CDC/NIOSH and employees of CDC contractors.

Operator means any owner, lessee, or other person who operates, controls, or supervises an underground coal mine or any independent contractor performing services or construction at such mine.

Panel of B Readers means the group of physicians that are currently approved by NIOSH as B Readers.

Pre-placement physical examination means any medical examination that includes a chest radiographic examination given in accordance with the specifications of this Part to a person not previously employed by the same operator. Such examinations should be conducted consistent with applicable law, including the Americans with Disabilities Act of 1990, which provides that pre-placement examinations take place only after an offer of employment has been made and subject to certain restrictions (42 U.S.C. 12112(d)).

Qualified medical physicist means an individual who is trained in evaluating the performance of radiographic equipment including radiation controls and facility quality assurance programs, and has the relevant current certification by a competent U.S. national board, or unrestricted license or approval from a U.S. State or territory.

Radiographic technique chart means a table that specifies the types of cassette, intensifying screen, film or digital detector, grid, filter, and lists X-ray machine settings (timing, kVp, mA) that enables the radiographer to select the correct settings based on the body habitus or the thickness of the chest tissue.

Radiologic technologist means an individual who has met the requirements for privileges to perform general radiographic procedures and for competence in using the equipment and software employed by the examining facility to obtain chest images as specified by the State or Territory and examining facility in which such services are provided. Optimally, such an individual will have completed a formal training program in radiography leading to a certificate, an associate degree, or a bachelor's degree and participated in the voluntary initial certification and annual renewal of registration for radiologic technologists offered by the American Registry of Radiologic Technologists.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

Soft copy means the image of a coal miner's chest radiograph acquired using a digital radiography system, viewed at the full resolution of the image acquisition system using an

electronic medical image display device.

[77 FR 56726, Sept. 13, 2012]

§ 37.3 Chest radiographs required for miners.

(a) *Voluntary examinations.* Every operator must provide to each miner who is employed in or at any of its underground coal mines and who was employed in underground coal mining prior to December 30, 1969, or who has completed the required examinations under § 37.3(b) an opportunity for a chest radiograph in accordance with this subpart:

(1) Following August 1, 1978 NIOSH will notify the operator of each underground coal mine of a period within which the operator may provide examinations to each miner employed at its coal mine. The period must begin no sooner than October 15, 2012 and end no later than a date specified by NIOSH separately for each coal mine. The termination date of the period will be approximately 5 years from the date of the first examination that was made on a miner employed by the operator in its coal mine under the former regulations of this subpart adopted July 27, 1973. Within the period specified by NIOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.5.

Example: NIOSH finds that between July 27, 1973, and March 31, 1975, the first radiograph for a miner who was employed at mine Y and who was employed in underground coal mining prior to December 30, 1969, was made on January 1, 1974. NIOSH will notify the operator of mine Y that the operator may select and designate on its plan a 6-month period within which to offer its examinations to its miners employed at mine Y. The 6-month period must be scheduled between August 1, 1978 and January 1, 1979 (5 years after January 1, 1974).

(2) For all future voluntary examinations, NIOSH will notify the operator of each underground coal mine when sufficient time has elapsed since the end of the previous 6-month period of examinations. NIOSH will specify to the operator of each mine a period within which the operator may provide examinations to its miners employed at its coal mine. The period must begin no sooner than 3½ years and end no later than 4½ years subsequent to the ending date of the previous 6-month period specified for a coal mine either by the operator on an approved plan or by NIOSH if the operator did not submit an approved plan. Within the period specified by NIOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.5.

Example: NIOSH finds that examinations were previously provided to miners employed at mine Y in a 6-month period from July 1, 1979, to December 31, 1979. NIOSH notifies the operator at least 3 months before July 1, 1983 (3½ years after December 31, 1979) that the operator may select and designate on its plan the next 6-month period within which to offer examinations to its miners employed at mine Y. The 6-month period must be scheduled between July 1, 1983, and July 1, 1984 (between 3½ and 4½ years after December 31, 1979).

(3) Within either the next or future period(s) specified by NIOSH to the operator for each of its coal mines, the operator of the coal mine may select a different 6-month period for each of its mines within which to offer examinations. In the event the operator does not submit an approved plan, NIOSH will specify a 6-month period to the operator within which miners must have the opportunity for examinations.

(b) *Mandatory examinations.* Every operator must provide to each miner who begins working in or at a coal mine for the first time after December 30, 1969:

(1) An initial chest radiograph, as soon as possible, but in no event later than 6 months after commencement of employment. An initial chest radiograph given to a miner according to former regulations for this subpart prior to August 1, 1978 will also be considered as fulfilling this requirement.

(2) A second chest radiograph, in accordance with this subpart, 3 years following the initial examination if the miner is still engaged in underground coal mining. A second radiograph given to a miner according to former regulations under this subpart prior to August 1, 1978 will be considered as fulfilling this requirement.

(3) A third chest radiograph 2 years following the second chest radiograph

if the miner is still engaged in underground coal mining and if the second radiograph shows evidence of category 1 (1/0, 1/1, 1/2), category 2 (2/1, 2/2, 2/3), category 3 (3/2, 3/3, 3/+) simple pneumoconioses, or complicated pneumoconioses (ILO Classification).

(c) NIOSH will notify the miner when he or she is due to receive the second or third mandatory examination under (b) of this section. Similarly, NIOSH will notify the coal mine operator when the miner is to be given a second examination. The operator will be notified concerning a miner's third examination only with the miner's written consent, and the notice to the operator must not state the medical reason for the examination nor that it is the third examination in the series. If the miner is notified by NIOSH that the third mandatory examination is due and the operator is not so notified, availability of the radiographic examination under the Coal Mine Operator's Plan (Form CDC/NIOSH (M)2.10) will constitute the operator's compliance with the requirement to provide a third mandatory examination even if the miner refuses to take the examination.

(d) The opportunity for chest radiographs to be available by an operator for purposes of this subpart must be provided in accordance with a plan that has been submitted and approved in accordance with this subpart.

[77 FR 56726, Sept. 13, 2012]

§ 37.4 Plans for chest roentgenographic examinations.

(a) Every plan for chest radiographic examinations of miners must be submitted on the Coal Mine Operator's Plan form (Form CDC/NIOSH (M)2.10) to NIOSH within 120 calendar days after August 1, 1978. In the case of a person who after August 1, 1978, becomes an operator of a mine for which no plan has been approved, that person must submit a plan within 60 days after such event occurs. A separate plan must be submitted by the operator and by each construction contractor for each underground coal mine that has a MSHA identification number. The plan must include:

(1) The name, address, and telephone number of the operator(s) submitting the plan;

(2) The name, MSHA identification number for respirable dust measurements, and address of the mine included in the plan;

(3) The proposed beginning and ending date of the 6-month period for voluntary examinations (see § 37.3(a)), the estimated number of miners to be given or offered examinations during the 6-month period under the plan, and a roster specifying the names and current home mailing addresses of each miner covered by the plan;

(4) The name and location of the approved X-ray facility or facilities, and the approximate date(s) and time(s) of day during which the radiographs will be given to miners to enable a determination of whether the examinations will be conducted at a convenient time and place;

(5) If a mobile facility is proposed, the plan shall provide that each miner be given adequate notice of the opportunity to have the examination and that no miner shall have to wait for an examination more than 1 hour before or after his or her work shift. In addition, the plan shall include:

(i) The number of change houses at the mine.

(ii) One or more alternate nonmobile approved facilities for the reexamination of miners and for the mandatory examination of miners when necessary (see § 37.3(b)), or an assurance that the mobile facility will return to the location(s) specified in the plan as frequently as necessary to provide for examinations in accordance with these regulations.

(iii) The name and location of each change house at which examinations will be given. For mines with more than one change house, the examinations shall be given at each change house or at a change house located at a convenient place for each miner.

(6) The name and address of the A or B Reader who will interpret and classify the chest radiographs. In the event a plan lists an approved facility with a digital radiography system, the name and address of the physician(s) who will perform the initial clinical interpretation.

(7) Assurances that:

(i) The operator will not solicit a physician's radiographic or other findings concerning any miner employed by the operator,

(ii) Instructions have been given to the person(s) giving the examinations that duplicate radiographs or copies of radiographs (including, for digital radiographs, copies of electronic files) will not be made, and to the extent that it is technically feasible for the imaging system used, digital radiographs and all related digital files must be permanently deleted from the facility records or rendered permanently inaccessible following the confirmed transfer of such data to NIOSH, and that (except as may be necessary for the purpose of this subpart) the physician's radiographic and other findings, as well as the occupational history information obtained from a miner will not be disclosed in a manner that would permit identification of the individual with their information, and

(iii) The radiographic examinations will be made at no charge to the miner.

(b) Operators may provide for alternate facilities and ''A'' or ''B'' readers in plans submitted for approval.

(c) The change of operators of any mine operating under a plan approved pursuant to §37.5 shall not affect the plan of the operator which has transferred responsibility for the mine. Every plan shall be subject to revision in accordance with paragraph (d) of this section.

(d) The operator must advise NIOSH of any change in its plan. Each change in an approved plan is subject to the same review and approval as the originally approved plan.

(e) The operator must promptly display in a visible location on the bulletin board at the mine its proposed plan or proposed change in plan when it is submitted to NIOSH. The proposed plan or change in plan must remain posted in a visible location on the bulletin board until NIOSH either grants or denies approval of it at which time the approved plan or denial of approval must be permanently posted. In the case of an operator who is a construction contractor and who does not have a bulletin board, the construction contractor must otherwise notify its employees of the examination arrangements. Upon request, the contractor must show NIOSH written evidence that its employees have been notified.

(f) Upon notification from NIOSH that sufficient time has elapsed since the previous period of examinations, the operator will resubmit its plan for each of its coal mines to NIOSH for approval for the next period of examinations (see §37.3(a)(2)). The plan must include the proposed beginning and ending dates of the next period of examinations and all information required by paragraph (a) of this section.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978; 77 FR 56727, Sept. 13, 2012]

§37.5 Approval of plans.

(a) If, after review of any plan submitted pursuant to this subpart, the Secretary determines that the action to be taken under the plan by the operator meets the specifications of this subpart and will effectively achieve its purpose, the Secretary will approve the plan and notify the operator(s) submitting the plan of the approval. Approval may be conditioned upon such terms as the Secretary deems necessary to carry out the purpose of §203 of the Act.

(b) Where the Secretary has reason to believe that he or she will deny approval of a plan the Secretary will, prior to the denial, give reasonable notice in writing to the operator(s) of an opportunity to amend the plan. The notice must specify the ground upon which approval is proposed to be denied.

(c) If a plan is denied approval, the Secretary must advise the operator(s) in writing of the reasons for the denial.

[77 FR 56728, Sept. 13, 2012]

§37.6 Chest roentgenographic examinations conducted by the Secretary.

(a) The Secretary will give chest radiographs or make arrangements with an appropriate person, agency, or institution to give the chest radiographs and with A or B Readers to interpret the radiographs required under this subpart in the locality where the miner resides, at the mine, or at a medical facility easily accessible to a mining community or mining communities, under the following circumstances:

(1) Where, in the judgment of the Secretary, due to the lack of adequate medical or other necessary facilities or personnel at the mine or in the locality where the miner resides, the required roentgenographic examination cannot be given.

(2) Where the operator has not submitted an approvable plan.

(3) Where, after commencement of an operator's program pursuant to an approved plan and after notice to the operator of his failure to follow the approved plan and, after allowing 15 calendar days to bring the program into compliance, the Secretary determines and notifies the operator in writing that the operator's program still fails to comply with the approved plan.

(b) The operator of the mine shall reimburse the Secretary or other person, agency, or institution as the Secretary may direct, for the cost of conducting each examination made in accordance with this section.

(c) All examinations given or arranged by the Secretary will comply with the time requirements of § 37.3. Whenever the Secretary gives or arranges for the examinations of miners at a time, a written notice of the arrangements will be sent to the operator who shall post the notice on the mine bulletin board.

(d) Operators of mines selected by NIOSH to participate in the National Study of Coal Workers' Pneumoconiosis (an epidemiological study of respiratory diseases in coal miners) and who agree to cooperate will have all their miners afforded the opportunity to have a chest radiograph required hereunder at no cost to the operator. For future examinations and for mandatory examinations each participating operator must submit an approvable plan.

[43 FR 33715, Aug. 1, 1978, as amended at 77 FR 56728, Sept. 13, 2012]

§ 37.7 Transfer of affected miner to less dusty area.

(a) Any miner who, in the judgment of the Secretary based upon the interpretation of one or more of the miner's chest radiographs, shows category 1 (1/0, 1/1, 1/2), category 2 (2/1, 2/2, 2/3), or category 3 (3/2, 3/3, 3/+) simple pneumoconioses, or complicated pneumoconioses (ILO Classification) must be afforded the option of transferring from his or her position to another position in an area of the mine where the concentration of respirable dust in the mine atmosphere is in compliance with the MSHA requirements in 30 CFR 90.3.

(b) Any transfer under this section shall be in accordance with the procedures specified in part 90 of title 30, Code of Federal Regulations.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978, as amended at 44 FR 23085, Apr. 18, 1979; 49 FR 7563, Mar. 1, 1984;77 FR 56728, Sept. 13, 2012]

§ 37.8 Radiographic examination at miner's expense.

Any miner who wishes to obtain an examination at the miner's own expense at an approved facility and to have the complete examination submitted to NIOSH may do so, provided that the examination is made no sooner than 6 months after the most recent examination of the miner submitted to NIOSH. NIOSH will provide an interpretation and report of the examinations made at the miner's expense in the same manner as if it were submitted under an operator's plan. Any change in the miner's transfer rights under the Act that may result from this examination will be subject to the terms of § 37.7.

[77 FR 56728, Sept. 13, 2012]

§ 37.10 Standards incorporated by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, NIOSH must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at NIOSH, Division of Respiratory Disease Studies, 1095 Willowdale Road, Morgantown, WV 26505. To arrange for an inspection at NIOSH, call 304–285–5749. Copies are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at

NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(b) American Association of Physicists in Medicine, Order Department, Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705, *http://www.aapm.org/pubs/reports:*

(1) AAPM On-Line Report No. 03, Assessment of Display Performance for Medical Imaging Systems, April 2005, into § 37.51(d) and (e).

(2) AAPM Report No. 14, Performance Specifications and Acceptance Testing for X-Ray Generators and Automatic Exposure Control Devices, Report of the Diagnostic X-Ray Imaging Committee Task Group on Performance Specifications and Acceptance Testing for X-Ray Generators and Automatic Exposure Control Devices, published by the American Institute of Physics for AAPM, January 1985, into §§ 37.42(h) and 37.44(g).

(3) AAPM Report No. 31, Standardized Methods for Measuring Diagnostic X-Ray Exposures, Report of Task Group 8, Diagnostic X-Ray Imaging Committee, published by the American Institute of Physics, July 1990, into § 37.44(g).

(4) AAPM Report No. 74, Quality Control in Diagnostic Radiology, Report of Task Group 12, Diagnostic X-Ray Imaging Committee, published by Medical Physics Publishing for AAPM, July 2002, into §§ 37.42(h), 37.43(f), and 37.44(g).

(5) AAPM Report No. 93, Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems, October 2006, into §§ 37.42(i) and 37.44(g).

(6) AAPM Report No. 116, An Exposure Indicator for Digital Radiography, Report of AAPM Task Group 116, published by AAPM, July 2009, into § 37.44(g).

(c) American College of Radiology, 1891 Preston White Dr., Reston, VA 20191, *http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Reference_Levels.pdf:*

(1) ACR Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging, Revised 2008 (Resolution 3), into §§ 37.42(i) and 37.44(g).

(2) [Reserved]

(d) International Labour Office, CH–1211 Geneva 22, Switzerland, *http://www.ilo.org/publns:*

(1) Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised Edition 2011, into §§ 37.50(a), 37.50(c), and 37.51(b).

(2) [Reserved]

(e) National Council on Radiation Protection and Measurements, NCRP Publications, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814–3095, Telephone (800) 229–2652, *http://www.ncrppublications.org:*

(1) NCRP Report No. 102, Medical X-ray, Electron Beam, and Gamma-Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance, and Use), issued June 30, 1989, into § 37.45.

(2) NCRP Report No. 105, Radiation Protection for Medical and Allied Health Personnel, issued October 30, 1989, into § 37.45.

(3) NCRP Report No. 147, Structural Shielding Design for Medical X-Ray Imaging Facilities, revised March 18, 2005, into § 37.45.

(f) National Electrical Manufacturers Association, 1300 N. 17th Street, Rosslyn, VA 22209, *http://medical.nema.org:*

(1) DICOM Standard PS 3.3–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 3: Information Object Definitions, copyright 2011, into § 37.42(i).

(2) DICOM Standard PS3.4–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 4: Service Class Specifications, copyright 2011, into § 37.42(i).

(3) DICOM Standard PS 3.10–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 10: Media Storage and File Format for Media Interchange, copyright 2011, into § 37.42(i).

(4) DICOM Standard PS 3.11–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 11: Media Storage Application Profiles, copyright 2011, into § 37.42(i).

(5) DICOM Standard PS 3.12–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 12: Media Formats and Physical Media for Media Interchange, copyright 2011, into §§ 37.42(i) and 37.44(a).

(6) DICOM Standard PS 3.14–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 14: Grayscale Standard Display Function, copyright 2011, into §§ 37.42(i)(5) and 37.51(d).

(7) DICOM Standard PS 3.16–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 16: Content Mapping Resource, copyright 2011, § 37.42(i).

[77 FR 56728, Sept. 13, 2012]

§ 37.20 Miner identification document.

As part of the radiographic examination, a Miner Identification Document (Form CDC/NIOSH (M)2.9) which includes an occupational history questionnaire must be completed for each miner at the facility where the radiograph is made at the same time the chest radiograph required by this subpart is given.

[77 FR 56729, Sept. 13, 2012]

SPECIFICATIONS FOR PERFORMING CHEST RADIOGRAPHIC EXAMINATIONS

§ 37.40 General provisions.

(a) The chest radiographic examination must be given at a convenient time and place.

(b) The chest radiographic examination consists of the chest radiograph, and a complete Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8), and Miner Identification Document (Form CDC/NIOSH (M)2.9).

(c) A radiographic examination must be made in a facility approved in accordance with § 37.43 or § 37.44. Chest radiographs of miners under this section must be performed:

(1) By or under the supervision of a physician who makes chest radiographs in the normal course of practice and who has demonstrated ability to make chest radiographs of a quality to best ascertain the presence of pneumoconiosis; or

(2) By a radiologic technologist as defined in § 37.2.

[77 FR 56729, Sept. 13, 2012]

§ 37.41 Chest radiograph specifications—film.

(a) Miners must be disrobed from the waist up at the time the radiograph is given. The facility must provide a dressing area and for those miners who wish to use one, the facility will provide a clean gown. Facilities must be heated to a comfortable temperature.

(b) Every chest radiograph must be a single posteroanterior projection at full inspiration on a film being no less than 14 by 17 inches and no greater than 16 by 17 inches. The film and cassette must be capable of being positioned both vertically and horizontally so that the chest radiograph will include both apices and costophrenic angles. If a miner is too large to permit the above requirements, then the projection must include both apices with minimum loss of the costophrenic angle.

(c) Chest radiographs of miners under this section must be performed:

(1) By or under the supervision of a physician who makes chest radiographs in the normal course of practice and who has demonstrated ability to make chest radiographs of a quality to best ascertain the presence of pneumoconiosis; or

(2) By a radiologic technologist as defined in § 37.2.

(d) Radiographs must be made with a diagnostic X-ray machine with a maximum actual (not nominal) source (focal spot) of 2 mm, as measured in two orthogonal directions.

(e) Except as provided in this paragraph (e), radiographs must be made with units having generators that comply with the following:

(1) The generators of existing radiographic units acquired by the examining facility prior to July 27, 1973, must have a minimum rating of 200 mA at 100 kVp;

(2) Generators of units acquired subsequent to that date must have a minimum rating of 300 mA at 125 kVp.

(f) Radiographs made with battery-powered mobile or portable equipment must be made with units having a minimum rating of 100 mA at 110 kVp at 500 Hz, or of 200 mA at 110 kVp at 60 Hz.

(g) Capacitor discharge and field emission units may be used if the model of such units is approved by NIOSH for quality, performance, and safety. NIOSH will consider such units for approval when listed by a facility seeking approval under §§ 37.43 or 37.44.

(h) Radiographs must be given only with equipment having a beam-limiting device that does not cause large unexposed boundaries. The beam limiting device must provide rectangular collimation and must be of the type described in 21 CFR 1020.31(d), (e), (f), and (g). The use of such a device must be discernible from an examination of the radiograph.

(i) To ensure high quality chest radiographs:

(1) The maximum exposure time must not exceed 50 milliseconds except that with single phase units with a rating less than 300 mA at 125 kVp and subjects with chests over 28 cm posteroanterior, the exposure may be increased to not more than 100 milliseconds;

(2) The source or focal spot to film distance must be at least 6 feet;

(3) Medium speed film and medium speed intensifying screens are recommended. However, any film-screen combination, the rated ''speed'' of which is at least 100 and does not exceed 300, that produces radiographs with spatial resolution, contrast, latitude and quantum mottle similar to those of systems designated as ''medium speed'' may be employed;

(4) Film-screen contact shall be maintained and verified at 6 month or shorter intervals;

(5) Intensifying screens shall be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer;

(6) All intensifying screens in a cassette shall be of the same type and made by the same manufacturer;

(7) A suitable grid or other means of reducing scattered radiation must be used;

(8) The geometry of the radiographic system shall insure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film;

(9) A formal quality assurance program shall be established at each facility.

(j) Radiographic processing:

(1) Either automatic or manual film processing is acceptable. A constant time-temperature technique shall be meticulously employed for manual processing.

(2) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality radiograph, a suitable filter or purification system must be used.

(k) Before the miner is advised that the examination is concluded, the radiograph must be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard radiograph, another must be immediately made. All substandard radiographs must be clearly marked as rejected and promptly sent to NIOSH for disposal.

(l) An electric power supply shall be used which complies with the voltage, current, and regulation specified by the manufacturer of the machine.

(m) A test object may be required on each radiograph for an objective evaluation of film quality at the discretion of NIOSH.

(n)(1) Each radiograph made hereunder must be permanently and legibly marked with:

(i) The name and address or NIOSH approval number of the facility at which it is made;

(ii) The miner's Social Security number;

(iii) The miner's date of birth; and

(iv) The date of the radiograph.

(2) No other identifying markings may be recorded on the radiograph.

[43 FR 33715, Aug. 1, 1978, as amended at 52 FR 7866, Mar. 13, 1987; 77 FR 56729, Sept. 13, 2012]

§ 37.42 Chest radiograph specifications—digital radiography systems.

(a) Miners must be disrobed from the waist up at the time the radiograph is given. The facility must provide a private dressing area and for those miners who wish to use one, the facility must provide a clean gown. Facilities must be heated to a comfortable temperature.

(b) Every digital chest radiograph taken as required under this section must be a single posteroanterior projection at full inspiration on a digital detector with sensor area being no less than 1505 cm square centimeters with a

minimum width of 35cm. The imaging plate must have a maximum pixel pitch of 200μm, with a minimum bit depth of 10. Spatial resolution must be at least 2.5 line pairs per millimeter. The storage phosphor cassette or digital image detector must be positioned either vertically or horizontally so that the image includes the apices and costophrenic angles of both right and left lungs. If the detector cannot include the apices and costophrenic angles of both lungs as described, then two side-by-side images can be obtained that together include the apices and the costophrenic angles of both right and left lungs.

(c) Chest radiographs of miners under this section must be performed:

(1) By or under the supervision of a physician who makes chest radiographs in the normal course of practice and who has demonstrated ability to make chest radiographs of a quality to best ascertain the presence of pneumoconiosis; or

(2) By a radiologic technologist as defined in § 37.2.

(d) Radiographs must be made with a diagnostic X-ray machine with a maximum actual (not nominal) source (focal spot) of 2 mm, as measured in two orthogonal directions.

(e) Radiographs must be made with units having generators which have a minimum rating of 300 mA at 125 kVp. Exposure kilovoltage must be at least the minimum as recommended by the manufacturer for chest radiography.

(f) An electric power supply must be used that complies with the voltage, current, and regulation specified by the manufacturer of the machine. If the manufacturer or installer of the radiographic equipment recommends equipment for control of electrical power fluctuations, such equipment must be used as recommended.

(g) Radiographs must be obtained only with equipment having a beam-limiting device that does not cause large unexposed boundaries. The beam limiting device must provide rectangular collimation. Electronic post-image acquisition ''shutters'' available on some CR and DR systems that limit the size of the final image and that simulate collimator limits must not be used. The use and effect of the beam limiting device must be discernible on the resulting image.

(h) Radiographic technique charts must be used that are developed specifically for the X-ray system and detector combinations used, indicating exposure parameters by anatomic measurements.

(1) If automated exposure control devices are used, performance must be documented by a medical physicist utilizing the image capture systems and exposure parameters used at the facility for chest imaging, using methods recommended in AAPM Report No. 74, pages 17–18, and in AAPM Report No. 14, pages 61–62 (incorporated by reference, see § 37.10).

(2) Exposure parameters achieved during the evaluation of the automated exposure system must be recorded by the medical physicist in a written report or electronic file that is stored at the facility and available for inspection by NIOSH for a minimum of 5 years after the miner's examination.

(i) To ensure high quality digital chest radiographs:

(1) The maximum exposure time must not exceed 50 milliseconds except for subjects with chests over 28 centimeters posteroanterior, for whom the exposure time must not exceed 100 milliseconds;

(2) The distance from source or focal spot to detector must be at least 70 inches (or 180 centimeters if measured in centimeters);

(3) The exposure setting for chest images must be within the range of 100–300 equivalent exposure speeds and must comply with ACR Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging, Section V—Diagnostic Reference Levels For Imaging With Ionizing Radiation and Section VII—Radiation Safety in Imaging (incorporated by reference, see § 37.10). Radiation exposures should be periodically measured and patient radiation doses estimated by the medical physicist to assure doses are as low as reasonably achievable.

(4) Digital radiography system performance, including resolution, modulation transfer function (MTF), image signal-to-noise and detective quantum efficiency must be evaluated and

judged acceptable by a qualified medical physicist using the specifications in AAPM Report No. 93, pages 1–68 (incorporated by reference, see §37.10). Image management software and settings for routine chest imaging must be used, including routine amplification of digital detector signal as well as standard image post-processing functions. Image or edge enhancement software functions must not be employed unless they are integral to the digital radiography system (not elective); in such cases, only the minimum image enhancement permitted by the system may be employed.

(5)(i) The image object, transmission and associated data storage, file format, and transmission of associated information must conform to the following components of the Digital Imaging and Communications in Medicine (DICOM) standard (incorporated by reference, see §37.10):

(A) DICOM Standard PS 3.3–2011, Annex A—Composite Information Object Definitions, sections: Computed Radiography Image Information Object Definition; Digital X-Ray Image Information Object Definition; X-Ray Radiation Dose SR Information Object Definition; and Grayscale Softcopy Presentation State Information Object Definition.

(B) DICOM Standard PS3.4–2011, Annex B—Storage Service Class; Annex N—Softcopy Presentation State Storage SOP Classes; Annex O—Structured Reporting Storage SOP Classes.

(C) DICOM Standard PS 3.10–2011.

(D) DICOM Standard PS 3.11–2011

(E) DICOM Standard PS 3.12–2011.

(F) DICOM Standard PS 3.14–2011.

(G) DICOM Standard PS 3.16–2011.

(ii) Identification of each miner, chest image, facility, date and time of the examination must be encoded within the image information object, according to DICOM Standard PS 3.3–2011, Information Object Definitions, for the DICOM ''DX'' object. If data compression is performed, it must be lossless. Exposure parameters (kVp, mA, time, beam filtration, scatter reduction, radiation exposure) must be stored in the DX information object.

(iii) Exposure parameters as defined in the DICOM Standard PS 3.16–2011 must additionally be provided, when such parameters are available from the facility digital image acquisition system or recorded in a written report or electronic file and either transmitted to NIOSH or stored at the facility and available for inspection by NIOSH for 5 years after the examination.

(6) A specific test object may be required on each radiograph for an objective evaluation of image quality at the discretion of NIOSH.

(7) CR imaging plates must be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer;

(8) A grid or air gap for reducing scattered radiation must be used; grids must not be used that cause Moiré interference patterns in either horizontal or vertical images.

(9) The geometry of the radiographic system must ensure that the central axis (ray) of the primary beam is perpendicular to the plane of the CR imaging plate, or DR detector and is correctly aligned to the grid;

(10) Radiographs must not be made when the environmental temperatures and humidity in the facility are outside the manufacturer's recommended range of the CR and DR equipment to be used.

(11) Before the miner is advised that the examination is concluded, the radiograph must be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard radiograph, another must be made immediately. Unacceptable digital image files must be fully deleted immediately or rendered permanently inaccessible in the event that permanent deletion is not technologically feasible.

(j) The following are not authorized for use under this section:

(1) Digital images derived from film screen chest radiographs (e.g., by scanning or digital photography); or

(2) Images that were acquired using digital systems and then printed on transparencies for back-lighted display (e.g., using tradition view boxes).

[77 FR 56730, Sept. 13, 2012]

§ 37.43 Approval of radiographic facilities that use film.

(a) Facilities become eligible to participate in this program by demonstrating their ability to make high quality diagnostic chest radiographs by submitting to NIOSH six or more sample chest radiographs made and processed at the applicant facility and which are of acceptable quality to one or more individuals selected by NIOSH from the panel of B Readers. Applicants must also submit a radiograph of a plastic step-wedge object[1] or other test object (available on loan from NIOSH) that was made and processed at the same time with the same technique as the radiographs submitted and processed at the facility for which approval is sought. At least one chest radiograph and one test object radiograph must have been made with each unit to be used hereunder. All radiographs must have been made within 15 calendar days prior to submission and must be marked to identify the facility where each radiograph was made, the X-ray machine used, and the date each was made. The chest radiographs will be returned and may be the same radiographs submitted pursuant to § 37.50.

(b) Each radiographic facility submitting chest radiographs for approval under this section must complete and include an X-ray Facility Certification Document (Form CDC/NIOSH (M) 2.11) describing each X-ray unit to be used to make chest radiographs under the Act. The form must include:

(1) The date of the last radiation safety inspection by an appropriate licensing agency or, if no such agency exists, by a qualified expert as defined in NCRP Report No. 102 (incorporated by reference, see § 37.10);

(2) The deficiencies found;

(3) A statement that all the deficiencies have been corrected; and

(4) The date of acquisition of the X-ray unit. To be acceptable, the radiation safety inspection must have been made within 1 year preceding the date of application.

(c) Radiographs submitted with applications for approval under this section will be evaluated by one or more individuals selected by NIOSH from the panel of B Readers or by a qualified medical physicist or consultant. Applicants will be advised of any reasons for denial of approval.

(d) NIOSH or its representatives may make a physical inspection of the applicant's facility and any approved radiographic facility at any reasonable time to determine if the requirements of this subpart are being met.

(e) NIOSH may require a facility periodically to resubmit radiographs of a test object, sample radiographs, or a Facility Certification Document for quality control purposes. Approvals granted hereunder may be suspended or withdrawn by notice in writing when in the opinion of NIOSH the quality of radiographs or information submitted under this section warrants such action. A copy of a notice withdrawing approval will be sent to each operator who has listed the facility as its facility for giving chest radiographs and must be displayed on the mine bulletin board adjacent to the operator's approved plan. The approved plan will be reevaluated by NIOSH in light of this change.

(f) A formal written quality assurance program must be established at each facility addressing radiation exposures, equipment maintenance, and image quality, and must conform to the standards in AAPM Report No. 74, pages 1–19, 47–53, and 56 (incorporated by reference, see § 37.10).

(g) In conducting medical examinations pursuant to this Part, physicians and radiographic facilities must maintain the results and analysis of these examinations (including any hard copies or digital files containing individual data, interpretations, and images) consistent with applicable statutes and regulations governing the treatment of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR part 160 and subparts A, C, and E of part 164).

[77 FR 56731, Sept. 13, 2012]

[1] The plastic step-wedge object is described in Trout ED, Kelley JP [1973]. A phantom for the evaluation of techniques and equipment used for roentgenography of the chest. Amer J Roentgenol 117(4):771–776.

§ 37.44 Approval of radiographic facilities that use digital radiography systems.

(a) *Applications for facility approval.* (1) Facilities seeking approval must demonstrate the ability to make high quality digital chest radiographs by submitting to NIOSH digital radiographic image files of a test object (*e.g.*, a plastic step-wedge or chest phantom which will be provided on loan from NIOSH) as well as digital radiographic image files from six or more sample chest radiographs that are of acceptable quality to one or more individuals selected by NIOSH from the panel of B Readers and a qualified medical physicist or consultant, both designated by NIOSH. Image files must be submitted on standard portable media (compact or digital video disc) and formatted to meet specifications of the Digital Imaging and Communications in Medicine (DICOM) standard PS 3.12–2011 (incorporated by reference, see § 37.10). Applicants will be advised of any reasons for denial of approval. All submitted images must be made within 60 days prior to the date of application using the same technique, equipment, and software as will be used by the facility under the requested approval. At least six chest radiographs and one test object radiograph must have been made with each digital radiographic unit to be used by the facility under the requested approval. The corresponding radiographic image files must be submitted on standard portable media (compact or digital video disc) and formatted to meet specifications of the current DICOM Standard PS 3.12–2011. Documentation must include the following: the identity of the facility where each radiograph was made; the X-ray machine used; and the model, version, and production date of each image acquisition software program and hardware component. The submitted sample digital chest image files must include at least two taken with the detector in the vertical position and two in the horizontal position where the imaging system permits these positions, and at least two chest images must be from persons within the highest quartile of chest diameters (28 cm or greater).

(2) Each radiographic facility submitting chest radiographic image files for approval under this section must complete and include an X-ray Facility Certification Document (Form CDC/NIOSH (M)2.11) describing each X-ray system component, and the models and versions of image acquisition hardware and software to be used to make digital chest radiographs under the Act. The form must include:

(i) A copy of a dated report signed by a qualified medical physicist, documenting the evaluation of radiation safety and performance characteristics specified in this section for each digital radiography system;

(ii) A copy of the report of the most recent radiation safety inspection by a licensing agency, if such agency exists;

(iii) A listing of all deficiencies noted in either of the reports;

(iv) A statement that all the listed deficiencies have been corrected; and

(v) The names and relevant training and experience of facility personnel described in paragraphs (b), (d), and (e) of this section. To be acceptable, the report by the medical physicist and radiation safety inspection specified in this paragraph must have been made within 1 year prior to the date of submission of the application.

(b) Facilities must maintain ongoing licensure and certification under relevant local, State, and Federal laws and regulations for all digital equipment and related processes covered under this part.

(c) NIOSH or its representatives may make a physical inspection of the applicant's facility and any approved radiographic facility at any reasonable time to determine if the requirements of this subpart are being met.

(d) NIOSH may periodically require a facility to resubmit radiographic image files of the NIOSH-supplied test object (*e.g.*, step-wedge or chest phantom), sample radiographs, or a Facility Certification Document. Approvals granted to facilities under this section may be suspended or withdrawn by notice in writing when, in the opinion of NIOSH, deficiencies in the quality of radiographs or information submitted under this section warrant such action. A copy of a notice suspending or withdrawing approval will be sent to each

operator that has listed the facility for its use under this Part and must be displayed on the mine bulletin board adjacent to the operator's approved plan. The operator's approved plan may be reevaluated by NIOSH in response to such suspension or withdrawal.

(e) A qualified medical physicist who is familiar with the facility hardware and software systems for image acquisition, manipulation, display, and storage, must be on site or available as a consultant. The physicist must be trained in evaluating the performance of radiographic equipment and facility quality assurance programs, and must be licensed/approved by a State or Territory of the United States or certified by a competent U.S. national board.

(f) Facilities must document that testing performed by a qualified medical physicist has verified that performance of each image acquisition system for which approval is sought met initial specifications and standards of the equipment manufacturer and performance testing as required under paragraphs (b), (e), and (g) of this section.

(g) A formal written quality assurance program must be established at each facility addressing radiation exposures, equipment maintenance, and image quality, and must conform to the standards in AAPM Report No. 74, pages 1–19, 47–53, and 56, and AAPM Report No. 116, sections VIII, IX, and X (incorporated by reference, see § 37.10).

(1) Applications for facility approval must include a comprehensive assessment by a qualified medical physicist within 12 months prior to application addressing the performance of X-ray generators, automatic exposure controls, and image capture systems. The assessment must comply with the following guidelines: AAPM Report No. 93, pages 1–68; AAPM Report No. 74, pages 6–11; and AAPM Report No. 14, pages 1–96 (incorporated by reference, see § 37.10).

(2) Radiographic technique charts must be used that are developed specifically for the X-ray system and detector combinations used, indicating exposure parameters by anatomic measurements. If automated exposure control devices are used, calibration for chest imaging must be documented using the actual voltages and image capture systems. Radiological exposures resulting from at least ten (randomly selected) digital chest images obtained at the facility must be monitored at least quarterly to detect and correct potential dose creep, using methods specified in AAPM Report No. 31 (incorporated by reference, see § 37.10). Radiation exposures must be compared to a professionally accepted reference level published in the American College of Radiology (ACR) Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging, pages 1–6 (incorporated by reference, see § 37.10). In addition, the medical physicist must submit an annual assessment of measured or estimated radiation exposures, with specific recommended actions to minimize exposures during examinations performed under this part.

(3) For each digital radiography device and system, performance must be monitored annually in accordance with the recommendations of AAPM Report No. 93 (incorporated by reference, see § 37.10), except for the testing specifically excluded below. Documentation must be maintained on the completion of quality assurance testing, including the reproducibility of X-ray output, linearity and reproducibility of mA settings, accuracy and reproducibility of timer and kVp settings, accuracy of source-to-detector distance, and X-ray field focal spot size, selection, beam quality, congruence and collimation. For DR systems, the following tests listed in AAPM Report No. 93 are not required under this part:

(i) Section 8.4.5: Laser beam function
(ii) Section 8.4.9: Erasure Thoroughness
(iii) Section 8.4.11: Imaging Plate (IP) Throughput

(4) Facilities must maintain documentation, available for inspection by NIOSH for 5 years, of the ongoing implementation of policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of chest image acquisition, digitization, processing, compression, transmission, display, archiving, and retrieval functions of digital radiography devices and systems.

(h) In conducting medical examinations pursuant to this Part, physicians and radiographic facilities must maintain the results and analysis of these examinations (including any hard copies or digital files containing individual data, interpretations, and images) consistent with applicable statutes and regulations governing the treatment of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR Part 160 and Subparts A, C, and E of Part 164).

[77 FR 56732, Sept. 13, 2012]

§ 37.45 Protection against radiation emitted by radiographic equipment.

Except as otherwise specified in § 37.41 and § 37.42, radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used, must conform to applicable State or Territorial and Federal regulations. Where no applicable regulations exist, radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used must conform to the recommendations in NCRP Report No. 102, NCRP Report No. 105, and NCRP Report No. 147 (incorporated by reference, see § 37.10).

[77 FR 56733, Sept. 13, 2012]

SPECIFICATIONS FOR INTERPRETATION, CLASSIFICATION, AND SUBMISSION OF CHEST RADIOGRAPHS

§ 37.50 Interpreting and classifying chest radiographs—film.

(a) Chest radiographs must be interpreted and classified in accordance with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10). Chest radiograph interpretations and classifications must be recorded on a paper or electronic Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8).

(b) Radiographs must be interpreted and classified only by a physician who reads chest radiographs in the normal course of practice and who has demonstrated proficiency in classifying the pneumoconioses in accordance with § 37.52.

(1) Initial clinical interpretations and notification of findings other than pneumoconiosis under § 37.50(a) must be provided by a qualified physician who has all required licensure and privileges, and interprets chest radiographs in the normal course of practice.

(2) [Reserved]

(c) All interpreters, whenever interpreting chest radiographs made under the Act, must have immediately available for reference a complete set of the standard radiographs for use with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10).

(d) In all view boxes used for making interpretations:

(1) Fluorescent lamps must be simultaneously replaced with new lamps at 6-month intervals;

(2) All the fluorescent lamps in a panel of boxes must have identical manufacturer's ratings as to intensity and color;

(3) The glass, internal reflective surfaces, and the lamps must be kept clean;

(4) The unit must be so situated as to minimize front surface glare.

[77 FR 56733, Sept. 13, 2012]

§ 37.51 Interpreting and classifying chest radiographs—digital radiography systems.

(a) For each chest radiograph obtained at an approved facility using a digital radiography system, a qualified and licensed physician who reads chest radiographs in the normal course of practice must provide an initial clinical interpretation and notification, as specified in § 37.54, of any significant abnormal findings other than pneumoconiosis.

(b) Chest radiographs must be classified for pneumoconiosis by physician readers who have demonstrated ongoing proficiency, as specified in § 37.52(b), in classifying the pneumoconioses in a manner consistent with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10). Chest radiograph interpretations and classifications must be recorded on a paper or electronic Roentgenographic

Interpretation Form (Form CDC/NIOSH (M)2.8).

(c) All interpreters, whenever classifying digitally-acquired chest radiographs made under the Act, must have immediately available for reference a complete set of NIOSH-approved standard digital chest radiographic images provided for use with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10). Only NIOSH-approved standard digital images may be used for classifying digital chest images for pneumoconiosis. Modification of the appearance of the standard images using software tools is not permitted.

(d) Viewing systems should enable readers to display the coal miner's chest image at the full resolution of the image acquisition system, side-by-side with the selected NIOSH-approved standard images for comparison.

(1)(i) Image display devices must be flat panel monitors displaying at least 3 MP at 10 bit depth. Image displays and associated graphics cards must meet the calibration and other specifications of the Digital Imaging and Communications in Medicine (DICOM) P='56734'≤standard PS 3.14–2011 (incorporated by reference, see § 37.10).

(ii) Image displays and associated graphics cards must not deviate by more than 10 percent from the grayscale standard display function (GSDF) when assessed according to the AAPM On-Line Report No. 03, pages 1–146 (incorporated by reference, see § 37.10).

(2) Display system luminance (maximum and ratio), relative noise, linearity, modulation transfer function (MTF), frequency, and glare should meet or exceed recommendations listed in AAPM On-Line Report No. 03, pages 1–146 (incorporated by reference, see § 37.10). Viewing displays must have a maximum luminance of at least 171 cd/m^2, a ratio of maximum luminance to minimum luminance of at least 250, and a glare ratio greater than 400. The contribution of ambient light reflected from the display surface, after light sources have been minimized, must be included in luminance measurements.

(3) Displays must be situated so as to minimize front surface glare. Readers must minimize reflected light from ambient sources during the performance of classifications.

(4) Measurements of the width and length of pleural shadows and the diameter of opacities must be taken using calibrated software measuring tools. If permitted by the viewing software, a record must be made of the presentation state(s), including any noise reduction and edge enhancement or restoration functions that were used in performing the classification, including any annotations and measurements.

(e) Quality control procedures for devices used to display chest images for classification must comply with the recommendations of the American Association of Physicists in Medicine AAPM On-Line Report No. 03, pages 1–146 (incorporated by reference, see § 37.10).

(1) If automatic quality assurance systems are used, visual inspection must be performed using one or more test patterns recommended by the medical physicist every 6 months, or more frequently, to check for defects that automatic systems may not detect.

(2) [Reserved]

(f) Classification of CR and DR digitally-acquired chest radiographs under this Part must be performed based on the viewing of images displayed as soft copies using the viewing workstations specified in this section. Classification of radiographs must not be based on the viewing of hard copy printed transparencies of images that were digitally-acquired.

(g) The classification of chest radiographs based on digitized copies of chest radiographs that were originally acquired using film-screen techniques is not permissible under this part.

[77 FR 36733, Sept. 13, 2012]

§ 37.52 Proficiency in the use of systems for classifying the pneumoconioses.

(a) First or A Readers:

(1) Approval as an A Reader must continue if established prior to October 15, 2012.

(2) Physicians who desire to be A Readers must demonstrate their proficiency in classifying the pneumoconioses by either:

(i) Submitting to NIOSH from the physician's files six sample chest radiographs which are considered properly classified by one or more individuals selected by NIOSH from the panel of B Readers. The six radiographs must consist of two without pneumoconiosis, two with simple pneumoconiosis, and two with complicated pneumoconiosis (these may be the same radiographs submitted for facility approval pursuant to § 37.43 and § 37.44). The films will be returned to the physician. The interpretations must be on the Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8), or;

(ii) Satisfactory completion, since June 11, 1970, of a course approved by NIOSH on the ILO International Classification of Radiographs of Pneumoconioses.

(b) Final or B Readers:

(1) Approval as a B Reader established prior to October 1, 1976, is hereby terminated.

(2) Proficiency in evaluating chest radiographs for radiographic quality and in the use of the ILO Classification for interpreting chest radiographs for pneumoconiosis and other diseases must be demonstrated by those physicians who desire to be B Readers by taking and passing a specially-designed proficiency examination given on behalf of or by NIOSH at a time and place specified by NIOSH. Each physician who desires to take the digital version of the examination will be provided a complete set of the current NIOSH-approved standard reference digital radiographs. Physicians who qualify under this provision need not be qualified under paragraph (a) of this section.

(c) Physicians who wish to participate in the program must familiarize themselves with the necessary components for attainment of reliable classification of chest radiographs for the pneumoconioses[2] and apply using an Interpreting Physician Certification Document (Form CDC/NIOSH (M)2.12).

[77 FR 56734, Sept. 13, 2012]

§ 37.53 Method of obtaining definitive interpretations.

(a) All chest radiographs which are first interpreted by an A or B Reader will be submitted by NIOSH to a B Reader qualified as described in § 37.52. If there is agreement between the two interpretations, as described in paragraph (b) of this section, the result will be considered final and reported to MSHA for transmittal to the miner. When agreement is lacking, NIOSH must obtain a third interpretation from the panel of B Readers. If any two of the three interpretations demonstrate agreement, the result must be considered the final determination. If agreement is lacking among the three interpretations, NIOSH will obtain independent classifications from two additional B Readers selected from the panel, and the final determination will be the median category derived from the total of five classifications.

(b) Two interpretations must be considered to be in agreement when they are derived from complete classifications recorded using approved paper or electronic versions of the Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8) and received by NIOSH, and both find either stage A, B, or C complicated pneumoconiosis, or, for simple pneumoconiosis, are both in the same major category or (with one exception noted below) are within one minor category (ILO Classification 12-point scale) of each other. In the last situation, the higher of the two interpretations must be reported. The only exception to the one minor category principle is a reading sequence of 0/1, 1/0, or 1/0, 0/1, which is not considered agreement.

[77 FR 56734, Sept. 13, 2012]

§ 37.54 Notification of abnormal radiographic findings.

(a) Findings of, or findings suggesting, abnormality of cardiac shape or size, tuberculosis, lung cancer, or any other significant abnormal findings other than pneumoconiosis must be communicated by the first physician

[2] NIOSH Safety and Health Topic. Chest Radiography: Radiographic Classification [*http://www.cdc.gov/niosh/topics/chestradiography/radiographic-classification.html*]. Date accessed: June 27, 2012.

to interpret the radiograph to the miner indicated on the Miner Identification Document or to the miner's designated physician. A notice of the communication must be submitted to NIOSH. When significant abnormal findings are reported, NIOSH will also notify the miner to contact his or her physician.

(b) In addition, when NIOSH has more than one radiograph of a miner in its files and the most recent examination was found by the first physician to interpret the radiograph or subsequently by NIOSH B Readers to show an abnormality of cardiac shape or size, tuberculosis, cancer, complicated pneumoconiosis, and any other significant abnormal findings, NIOSH will arrange for a licensed physician to compare the most recent image and interpretation to older images and NIOSH will inform the miner of any significant changes or progression of disease or other findings.

(c) All final findings regarding pneumoconiosis will be sent to the miner by MSHA in accordance with section 203 of the Act (see 30 CFR part 90). Positive findings with regard to pneumoconiosis will be reported to the miner or to the miner's designated physician by NIOSH.

(d) NIOSH will make every reasonable effort to process the findings described in paragraph (c) of this section within 60 days of receipt of the information described in § 37.60 in a complete and acceptable form. The information forwarded to MSHA will be in a form intended to facilitate prompt dispatch of the findings to the miner. The results of an examination made of a miner may not be processed by NIOSH if the examination was made within 6 months of the date of a previous acceptable examination.

[77 FR 56744, Sept. 13, 2012]

§ 37.60 Submitting required chest roentgenograms and miner identification documents.

(a) Each chest radiograph required to be made under this subpart, together with the completed Roentgenographic Interpretation Form and the completed Miner Identification Document, must be submitted together for each miner to NIOSH within 14 calendar days after the radiographic examination is given and become the property of NIOSH.

(1) When the radiograph is digital, the image file for each radiograph, together with either hard copy or electronic versions of the completed Roentgenographic Interpretation Form and the completed Miner Identification Document, must be submitted to NIOSH using the software and format specified by NIOSH either using portable electronic media, or a secure electronic file transfer within 14 calendar days after the radiographic examination. NIOSH will notify the submitting facility when it has received the image files and forms from the examination. After this notification, the facility will permanently delete, or if this is not technologically feasible for the imaging system used, render permanently inaccessible all files and forms from its electronic and physical files.

(2) [Reserved]

(b) If NIOSH deems any submission under paragraph (a) of this section inadequate, it will notify the operator of the deficiency. The operator must promptly make appropriate arrangements for the necessary reexamination.

(c) Failure to comply with paragraph (a) or (b) of this section will be cause to revoke approval of a plan or any other approval as may be appropriate. An approval that has been revoked may be reinstated at the discretion of NIOSH after it receives satisfactory assurances and evidence that all deficiencies have been corrected and that effective controls have been instituted to prevent a recurrence.

(d) Chest radiographs and other required documents must be submitted only for miners.

(e) If a miner refuses to participate in all phases of the examination prescribed in this subpart, no report need be made. If a miner refuses to participate in any phase of the examination prescribed in this subpart, all the forms shall be submitted with his or her name and social security account number on each. If any of the forms cannot be completed because of the miner's refusal, it shall be marked ''Miner Refuses,'' and shall be submitted. No submission shall be made, however, without a completed miner identification document containing the

miner's name, address, social security number and place of employment.

[43 FR 33715, Aug. 1, 1978, as amended at 77 FR 56735, Sept. 13, 2012]

REVIEW AND AVAILABILITY OF RECORDS

§ 37.70 Review of interpretations.

(a) Any miner who believes the interpretation for pneumoconiosis reported to him or her by MSHA is in error may file a written request with NIOSH that his or her radiograph be reevaluated. If the interpretation was based on agreement between an A Reader and a B Reader, NIOSH will obtain one or more additional interpretations by B Readers as necessary to obtain agreement in accord with §37.53, and MSHA must report the results to the miner together with notification from MSHA of any rights which may accrue to the miner in accordance with §37.7. If the reported interpretation was based on agreement between two (or more) B Readers, the reading will be accepted as conclusive and the miner must be so informed by MSHA.

(b) Any operator who is directed by MSHA to transfer a miner to a less dusty atmosphere based on the most recent examination made subsequent to August 1, 1978, may file a written request with NIOSH to review its findings. The standards set forth in paragraph (a) of this section apply and the operator and miner will be notified by MSHA whether the miner is entitled to the option to transfer.

[77 FR 56735, Sept. 13, 2012]

§ 37.80 Availability of records for radiographs.

(a) Medical information and radiographs on miners will be released by NIOSH only with the written consent from the miner, or if the miner is deceased, written consent from the miner's widow or widower, next of kin, or legal representative.

(b) To the extent authorized, radiographs will be made available for examination only at NIOSH.

[77 FR 56735, Sept. 13, 2012]

Subpart—Autopsies

AUTHORITY: Sec. 508, 83 Stat. 803; 30 U.S.C. 957.

SOURCE: 36 FR 8870, May 14, 1971, unless otherwise noted.

§ 37.200 Scope.

The provisions of this subpart set forth the conditions under which the Secretary will pay pathologists to obtain results of autopsies performed by them on miners.

§ 37.201 Definitions.

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Miner* means any individual who during his life was employed in any underground coal mine.

(c) *Pathologist* means

(1) A physician certified in anatomic pathology or pathology by the American Board of Pathology or the American Osteopathic Board of Pathology,

(2) A physician who possesses qualifications which are considered ''Board of eligible'' by the American Board of Pathology or American Osteopathic Board of Pathology, or

(3) An intern, resident, or other physician in a training program in pathology who performs the autopsy under the supervision of a pathologist as defined in paragraph (c) (1) or (2) of this section.

(d) *NIOSH* means the National Institute for Occupational Safety and Health, United States Public Health Service, Department of Health and Human Services, Post Office Box 4258, Morgantown, WV 26504.

[43 FR 33715, Aug. 1, 1978, as amended at 77 FR 56735, Sept. 13, 2012]

§ 37.202 Payment for autopsy.

(a) The Secretary will pay up to $200 to any pathologist who, after the effective date of the regulations in this part and with legal consent:

(1) Performs an autopsy on a miner in accordance with this subpart; and

(2) Submits the findings and other materials to NIOSH in accordance with this subpart within 180 calendar days after having performed the autopsy; and

(3) Receives no other specific payment, fee, or reimbursement in connection with the autopsy from the miner's widow, his family, his estate, or any other Federal agency.

(b) The Secretary will pay to any pathologist entitled to payment under paragraph (a) of this section and additional $10 if the pathologist can obtain and submits a good quality copy or original of a chest radiograph (posteroanterior view) made of the subject of the autopsy within 5 years prior to his death together with a copy of any interpretation made.

[35 FR 13206, Aug. 19, 1970, as amended at 38 FR 16353, June 22, 1973; 77 FR 56735, Sept. 13, 2012]

§ 37.203 Autopsy specifications.

(a) Every autopsy for which a claim for payment is submitted pursuant to this part:

(1) Shall be performed consistent with standard autopsy procedures such as those, for example, set forth in the ''Autopsy Manual'' prepared by the Armed Forces Institute of Pathology, July 1, 1960. (Technical Manual No. 8–300. NAVMED P–5065, Air Force Manual No. 160–19.) Copies of this document may be borrowed from ALFORD.

(2) Shall include:

(i) Gross and microscopic examination of the lungs, pulmonary pleura, and tracheobronchial lymph nodes;

(ii) Weights of the heart and each lung (these and all other measurements required under this subparagraph shall be in the metric system);

(iii) Circumference of each cardiac valve when opened;

(iv) Thickness of right and left ventricles; these measurements shall be made perpendicular to the ventricular surface and shall not include trabeculations or pericardial fat. The right ventricle shall be measured at a point midway between the tricuspid valve and the apex, and the left ventricle shall be measured directly above the insertion of the anterior papillary muscle;

(v) Size, number, consistency, location, description and other relevant details of all lesions of the lungs;

(vi) Level of the diaphragm;

(vii) From each type of suspected pneumoconiotic lesion, representative microscopic slides stained with hematoxylin eosin or other appropriate stain, and one formalin fixed, paraffin-impregnated block of tissue; a minimum of three stained slides and three blocks of tissue shall be submitted. When no such lesion is recognized, similar material shall be submitted from three separate areas of the lungs selected at random; a minimum of three stained slides and three formalin fixed, paraffin-impregnated blocks of tissue shall be submitted.

(b) Needle biopsy techniques shall not be used.

§ 37.204 Procedure for obtaining payment.

Every claim for payment under this subpart must be submitted to NIOSH and must include:

Every claim for payment under this subpart shall be submitted to ALFORD and shall include:

(a) An invoice (in duplicate) on the pathologist's letterhead or billhead indicating the date of autopsy, the amount of the claim and a signed statement that the pathologist is not receiving any other specific compensation for the autopsy from the miner's widow, his surviving next-of-kin, the estate of the miner, or any other source.

(b) Completed PHS Consent, Release and History form (Form CDC/NIOSH (M)2.6). This form may be completed with the assistance of the pathologist, attending physician, family physician, or any other responsible person who can provide reliable information.

(c) Report of autopsy:

(1) The information, slides, and blocks of tissue required by this subpart.

(2) Clinical abstract of terminal illness and other data that the pathologist determines is relevant.

(3) Final summary, including final anatomical diagnoses, indicating presence or absence of simple and complicated pneumoconiosis, and correlation with clinical history if indicated.

[43 FR 33715, Aug. 1, 1978, as amended at 77 FR 56735, Sept. 13, 2012]